K041011
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Attachment I
510(K) Summary
UltraLight II Nd:YAG Laser System

This 510(K) Summary of safety and effectiveness for the UltraLight II Nd:YAG Laser System is submitted in accordance with the requirements of the SMDA 1990 and following guidance concerning the organization and content of a 510(K) summary.

Applicant:	Sandstone Medical Technologies, LLC
Address:	Sandstone Medical Technologies LLC 516 Scott Street Homewood, AL 35209 USA
Contact Person:	Mr. Mark Rohrer
Telephone:	1-205-290-8251– Phone
Preparation Date:	April 15, 2004
Device Trade Name:	UltraLight II Nd:YAG Laser System
Common Name:	Nd:YAG Laser System
Classification Name:	Instrument, Surgical, Powered, laser 79-GEX, 21 CFR 878-48
Legally Marketed Predicate Device:	Clear Light ™ Nd:Yag Laser K003460 Medlite Laser System K970808, K983054 and K011677.
Description of the UltraLight II Nd:YAG Laser System:	The **UltraLight II Nd:YAG Laser System consists of a power supply unit with cooling, a footswitch and an umbilical cord that connects to the laser, which is located in the handpiece. In standard use, the handpiece is held against the treatment area and the light pulse is delivered when the footswitch is depressed. Laser parameters and other system features are controlled from the display panel located on the front of the power supply unit.**
Intended use of the UltraLight II Nd:YAG Laser System:	At the 1064 nm wavelength – dark ink tattoo removal, removal of pigmented lesions and the removal or lightening of hair. At the 532 nm wavelength – removal of red ink tattoos, treatment of vascular lesions including facial and leg veins, telangiectasis, angiomas, hemangiomas, port wine stains and most pigmented lesions (e.g. lentigines, ephildes)
Performance Data: Results of Clinical Study:	None None
Conclusion:	The UltraLight II Nd:YAG laser system is substantially equivalent to other existing Nd:YAG Laser Systems in commercial distribution for use in Dermatology and Plastic Surgery.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 14 2004

Sandstone Medical Technologies, LLC
c/o Ms. Connie White Hoy
908 Stetson Street
Woodland, California 95776

Re: K041011
Trade/Device Name: Sandstone Medical Technologies UltraLight II Nd:YAG Laser System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: October 28, 2004
Received: November 3, 2004

Dear Ms. Hoy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K Pending K041011 / S002

Device Name: Sandstone Medical Technologies UltraLight II Nd:YAG

Laser System

Indications For Use:

- **At the 1064 nm wavelength – dark ink tattoo removal, removal of pigmented lesions and the removal or lightening of hair.**
- **At the 532 nm wavelength – removal of red ink tattoos, treatment of vascular lesions including facial and leg veins, telangiectasias, angiomas, hemangiomas, port wine stains and most pigmented lesions (e.g. lentigines, ephildes)**

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K041011

Prescription Use xx AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)